Remarks

This Amendment is in response to the Office Action dated **June 24, 2003.**

Claim Rejections - 35 USC §112

Claims 14 and 28 have been rejected as indefinite. The rejection has been mooted by the cancellation of these claims. Note that cancellation does not affect the scope of the independent claims from which claims 14 and 29 depend. In particular, the "chain extender" term in claims 1 and 17, among other compounds, still encompasses the product Bruuggolen® M 1251 mentioned at page 8, lines 6-9.

Commercial literature pertaining to Bruuggolen® M 1251 is included in the supplemental IDS filed herewith.

Claim Rejections - 35 USC §103

Anderson et al in view of Loontjens I or Zahr

Claims 1-3, 5-9, 15-19, 21-23, 27, and 29-32 have been rejected as obvious from Anderson et al (US 5500180) in view of Loontjens I (US 6228980) or of Zahr (US 6504004).

The Office Action asserts that it would be obvious to use the chain extenders of Loontjens I or of Zahr in forming the Anderson et al balloons, the asserted motivation being to increase polymer viscosity. The applicant does not agree.

The Office Action cites Anderson et al as teaching balloon catheters from polyamides. Mention of "polyamide block copolymers" in Anderson et al does not constitute a teaching of polyamides, since polyamides are defined as polymers with amide repeat units while polyamide block copolymers typically include a substantial component of the polymer molecule for which this is not true. Hence, block polyamide block copolymers, as a whole, cannot properly be characterized as polyamides.

Anderson et al provides no basis for utilizing a composition as claimed. The sole mention of chain extenders in Anderson et al (Col. 8, line 37) is in connection with production of *polyurethane* block copolymers polymers, and is a description of starting materials for the polymer. There is no teaching or suggestion to prepare a melt mixture of a polymer and a chain

extender. Furthermore, there is no connection made between the starting materials for polyurethane block copolymers and any polyamide block copolymer. In fact there is no indication in Anderson et al, what polyamide block copolymers should be used, or how they can be obtained.

According to Anderson et al, balloons are to be formed from block copolymers which have a ratio of hard segments to soft segments which produces particular balloon properties (col. 8, lines 9-19). Loontjens I mentions the preparation of polyester-amide block copolymers, but there is no indication that such polymers will have a suitable ratio of hard and soft segments as demanded in Anderson et al. In fact, if the polyamide and polyester polymers used in the Loontjens I examples (nylon 6 and PET, respectively) were to be employed in preparing a block copolymer, the resulting block copolymer would likely be characterized as comprising *hard segments only*. A skilled person has no idea if some of the other polyamides and/or polyesters mentioned in col. 2, lines 18-41 might possibly meet Anderson's soft segment requirements, since Anderson what the hard segments and soft segments are. If one wanted to try to see if a block copolymer, which meets the requirements of Anderson et al, could be obtained in the manner of Loontjens I, extensive experimentation with many possible combinations of polyamides and polyesters, and with many different relative ratios, would have to be undertaken. There would be no reasonable basis to expect success in obtaining a polymer with the desired properties from such a program of experimentation, since one does not know whether one is even working with suitable polymer blocks in the first place.

Zahr does not describe or suggest use of its chain extenders with polyamide block copolymers at all. Thus this reference cannot be considered at all relevant to the polymers of Anderson et al. A basis for the combination is not found in any of these documents.

Still further, the Office Action asserts, as the alleged motivation for the combinations, that it would have been desirable to increase melt viscosity of a polyamide from which *catheters* are made in order to make the polyamides easier to handle in the extrusion step of the catheter production process. As understood, this statement is referring to Anderson's *balloons* of some hypothetical polyamide block copolymer.[1] Such a motivation cannot be found in the cited

[1] If this is incorrect, correction is requested in a subsequent non-final action, as no basis to switch from catheter balloons of Anderson et al to catheters has been stated.

references. Increasing melt viscosity increases the required pressure and/or temperature required for extrusion and may render more difficult the subsequent processing of an extruded tubular parison to a balloon. The skilled person has no reason to believe that increasing melt viscosity will make an extrusion step easier to handle. The expected increase in viscosity would be a reason to *avoid* chain extenders and chain extended polymers in forming balloon parisons, it is not a motivation to employ them.

In the case of the single polymer actually disclosed by Anderson et al, the polyurethane Pellethane ® 2363-75D, it is noted that neither Loontjens I nor Zahr teach or suggest use of their chain extenders with polyurethanes. Further, in Anderson's Example 1, the post extrusion processing to produce the desired balloons required three stretch and blow cycles, and a heat set step to obtain a balloon having the properties sought in this patent. Even then, those balloons had to be sterilized by a special process in order to provide the desired physical properties. Increasing the melt viscosity of the extrudate would likely render the parison even more resistant to blowing, so that still more stretch-blow cycles are required, if a balloon could be formed at all. The use of a chain extender also would alter the identity and ratio of the hard and soft segments of the polymer, such that the target balloon properties may no longer obtained, even with the special sterilization process. At least for these reasons, the skilled person clearly could not have had a reasonable expectation of success in forming a balloon as taught by Anderson et al, using Pellethane ® 2363-75D and a chain extender of Loontjens I (US 6228980) or of Zahr (US 6504004).

The basis for an expectation of success with a *polyamide* block copolymer is even less as there is no particular polymer to even start experimenting with.

The combination of references employed in rejecting the present application contains no suggestion or motivation which would lead a skilled person to employ a chain extender of Loontjens I or Zahr with a polyamide block copolymer, or with any other polymer or combination of polymers, to produce a balloon of the type described in Anderson et al. Nor could that combination disclosures have provided a basis to formulate reasonable expectation of success in employing any particular polyamide block copolymer and chain extender formulation to produce a catheter balloon. Therefore the applicant respectfully requests withdrawal of the rejection of claims 1-3, 5-9, 15-19, 21-23, 27, and 29-32 on Anderson et al in view of Loontjens

I or Zahr.

Anderson et al and Loontjens II

Claims 10-13 and 24-26 have been rejected on Anderson et al and Loontjens II (WO 96/34909). This is essentially the same rejection as the previous one, the difference being that Loontjes II describes bis-oxazolines as chain extenders, as is specifically relevant to these claims.

The rejection is traversed for the same reasons given above.

The polymers of Anderson et al and of Loontjens II are not the same. The Anderson et al polyamide block copolymers polymers are not identified. Loontjens II, like Zahr, does not mention polyamide block copolymers at all. Combination, therefore necessarily involves impermissible hindsight. Further, the asserted motivation for combination, again an improved handling of the extrusion due to increased viscosity, could not be reasonably be expected. The expected increase in viscosity is expected to make handling more difficult, hence a reason to *avoid* the use of the chain extenders of Loontjens II when preparing a balloon parison. Still further, the combined references fail to produce a reasonable expectation of success in obtaining a balloon with the properties as specified in the Anderson et al patent. At least for these reasons withdrawal of this rejection is requested.

Anderson et al and Loontjens II with Chen et al

Claims 4 and 20 have been rejected on Anderson et al and Loontjens II, further in view of Chen et al, (US 5554120), the latter being cited as teaching formulations of polyamides and polyolefins as balloon materials. The rejection relies on Anderson et al and Loontjens II in the same manner as the previous rejection and is therefore deficient at least for all of the reasons already given. Therefore, withdrawal of this rejection is likewise requested.

Conclusion

Claims 1-13, 15-27, and 29-34 are pending and are seen to be patentable over the art of record. The application is otherwise believed to be in condition for allowance. Allowance is requested.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: September 26, 2003

By: _____
Walter J. Steinkraus
Registration No.: 29592

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9185
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

f:\wpwork\wjs\10062us01_amd_20030909.doc